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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,720	12/01/2000	Steven K. H. Foug	2002850-0009	5311

7590 08/13/2003

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EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/728,720

Applicant(s)

FOUNG ET AL.

Examiner

Donna C. Wortman, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: Please see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


Donna C. Wortman, Ph.D.
Primary Examiner
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Applicant's proposed amendment after final has not been entered because entry would raises several new issues that would require further consideration and/or search, as well as an issue of new matter. For example, it is not immediately clear whether the proposed amendment to claims 1, 8, and 9 to recite "or binds to the same conformational epitopes as that bound by an antibody selected from the group consisting of ..." contains an informality and "epitopes" should be "epitope" in order to be grammatically consistent with "antibody," "binds" and the recitation of "an antibody" recited in the alternative, or whether "epitopes" is intended to encompass a broader scope for binding of conformational epitopes. Further, the proposed amendment to claims 25, 26, and 27 leaves the claims dependent from claim 4, which Applicant has proposed to cancel.

Although claim 23 is indicated to be an (Original) claim, it is presented in an altered form, and the proposed change in subject matter raises an issue of new matter since no support in the specification is pointed out for the proposed amendment.

The proposed amendment to claim 32 does not clarify whether or not all antibodies are within the scope of claim 1, and if not, raises a potential new matter issue since Applicant has not pointed out where support for administering a variety of antibodies can be found.

Claim 92 is indicated to be a (Previously amended) claim, but it is presented in an altered form, suggesting that it should be designated as (Currently amended). Claim 92 as proposed to be amended is at best ungrammatical and potentially indefinite, since it recites, e.g., "A combination of two or more antibodies that binds to two or more

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conformational epitopes ... wherein the antibodies are selected from ... or binds to the same conformational epitopes as that bound by an antibody ...". The noun "antibodies" does not agree in number with the verb "bind" and it is not clear what scope intended by "epitopes" since a given monoclonal antibody binds a single epitope.

Further, the Declaration under 35 U.S.C. 1.132 of Dr. Fount and the supporting exhibits will not be considered because they were not timely presented, since they are not directed solely to issues that were raised by the examiner for the first time in the final rejection; rejection of claims over Persson et al. was made in the first action on the merits. Further, even if the Declaration and exhibits were to be considered, it does not appear that they address subject matter commensurate in scope with at least claim 13, which recites "wherein the antibody competes with ... for binding to its epitope" since it would appear that the ability to compete with a monoclonal antibody for binding to an epitope does not necessarily require an antibody that is identical in binding specificity.

With respect to the rejection of record of claims 29, 30-32, 67, 70, and 98-100 under 35 USC 112, first paragraph, for reasons of record, Applicant has argued that additional antibodies that could be potentially be used therapeutically could be identified by testing them using assays as disclosed.

These arguments have been considered but not found persuasive, since there is no basis for predicting which antibodies would work, and since the necessity for both *in vitro* and *in vivo* testing for each and every antibody represents undue experimentation since Applicant has provided no basis for extrapolating from *in vitro* results to *in vivo* therapeutic success.

The provisional rejection of claims 1, 4-23, 25-29, 92-98, and 101-105 under the judicially created doctrine of obviousness-type double patenting over 09/430489 for reasons of record is maintained since no response is offered.

If entered, the proposed amendment to the specification at page 6 would have overcome the objection to the specification under 35 USC 132.

The proposed cancelation of claims 4-7, 10, 11, 96, 101, and 102, if entered, would have rendered moot all rejections of those claims. It is noted that claims 75-91 had been previously canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'D. Wortman', with a stylized flourish at the end.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
August 11, 2003